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Arizona State Board of Pharmacy

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New Board Compliance Officer

The Arizona State Board of Pharmacy Compliance staff expanded to our normal complement of five pharmacist Compliance personnel when Sandy Sutcliffe agreed to join the staff as a compliance officer. Sandy is a pharmacist who graduated from the school of pharmacy at Purdue University and she is also an attorney who graduated from the law school at Indiana University at Bloomington. Sandy is licensed as a pharmacist in Arizona and is also a member of the State Bar of Arizona. She will be responsible for inspections, complaints, and investigations in the north Phoenix and Scottsdale areas as well as Flagstaff.

Misbranded Prescriptions Result from a 'Diagnosis' by Internet Survey

At its November 17, 2004 Board meeting, the Board unanimously approved a letter drafted by the Board executive director and its assistant attorney general. The letter has recently been sent to the pharmacist-in-charge (PIC) at every pharmacy possessing a current permit issued by the Board. The letter warns pharmacists that dispensing a prescription known to have been issued by a prescriber pursuant to a diagnosis by a mail or Internet questionnaire or survey is prohibited by the Arizona Pharmacy Act. Such prescription medications are misbranded because they were dispensed without a valid prescription. The letter lists the applicable statutes and any questions about the letter may be addressed to the Board's executive or deputy director. The letter does not prevent the dispensing of medications pursuant to valid prescriptions such as when a patient utilizes electronic communications (e-mail) to make a request for refill(s) when a valid patient-prescriber relationship exists. The practice of telemedicine when a valid patient-prescriber relationship exists is also not affected.

Returning Dispensed Medications to a Pharmacy

It is important for all pharmacists to review the rules for accepting the return for resale of prescription medications previously dispensed by a pharmacy. Controlled substance medications may not be returned under any circumstances because federal (Drug Enforcement Administration) regulations currently prevent it. It may be helpful to consider dispensing of controlled substances as a "one-way street." Arizona Administrative Code R4-23-409 lists the circumstances under which dispensed non-controlled substance prescription medications may be returned to the **pharmacy where originally dispensed**. The rule enumerates the different sets of circumstances for different types of pharmacies. Community pharmacies have more stringent requirements than nursing home or hospital pharmacies. This is because the prescription medications dispensed to patients confined to hospitals and nursing homes are in the possession of licensed health care professionals at all times. Also, those facilities, unlike a patient's residence, are subject to inspection by federal and state authorities so that cleanliness and temperature are likely monitored and maintained. It is also imperative that pharmacists who accept a return of prescription medications previously dispensed by the pharmacy for resale pursuant to the rules remember to credit the payer(s) so that they are not guilty of claiming a fee for a product or service not ultimately delivered. It is important to keep in mind that a small but growing percentage of counterfeit drugs are introduced into the drug supply by this method. The existing rules require that the pharmacist make a determination that the medications returned for resale were not subject to misbranding, adulteration, contamination, or deterioration.

The Effects of the Flu Vaccine Shortage

In early October 2004, Chiron Corporation, one of two major pharmaceutical manufacturers of influenza vaccine, informed the Centers for Disease Control and Prevention (CDC) that it would be unable to distribute its estimated 48 million doses of Fluvirin® in time for the 2004-05 flu season. The United Kingdom's Medicines and Healthcare products Regulatory Agency temporarily suspended Chiron's license for its Liverpool facility that was scheduled to produce Fluvirin for distribution throughout the United States.

During the 2003-04 flu season, approximately 87 million doses of influenza vaccine were administered. Before Chiron's announcement, it was expected that 100 million doses would be available during this season, with Aventis, the other major influenza vaccine (Fluzone®) producer, contributing 54 million doses. Aventis has indicated that it will be able to produce an additional 2.6 million doses of influenza vaccine by January 2005.

Shortly after this announcement CDC convened its Advisory Committee on Immunization Practices to issue recommendations to prioritize the existing supply of influenza vaccine. In summary, the CDC recommends that the following priority groups be given available doses first due to their increased risk of complications from influenza infection:

- Persons aged 65 years or older;
- Children six to 23 months of age;
- Residents of long-term care facilities and nursing homes;
- Persons two to 64 years of age with chronic medical conditions;
- Health care workers involved in direct patient care;
- Household contacts and out-of-home caregivers of children less than six months of age;
- Children and teenagers between the ages of six months and 18 years who are receiving aspirin therapy; and
- Pregnant women.

Although not appropriate for everyone, FluMist® (MedImmune), the intranasal influenza vaccine, may be a good alternative for healthy persons between the ages of five and 49. Unlike Fluvirin and Fluzone injectables, which are inactivated influenza vaccines, FluMist is a live attenuated virus, which, if administered to at-risk groups, particularly those with compromised immune systems, may in rare instances actually cause disease.

Other alternatives include antiviral medications, which may be used to prevent and treat influenza infection. The antiviral agents rimantadine, Tamiflu® (oseltamivir), and amantadine are Food and Drug Administration (FDA) approved for treatment and prophylaxis of influenza. Relenza® (zanamivir) is only approved for influenza treatment. To help minimize resistance, CDC currently encourages the use of amantadine or rimantadine for influenza prevention while using the other antivirals oseltamivir or zanamivir for treatment.

Although vaccination and other pharmacologic interventions are extremely beneficial, health care professionals should educate patients on practical measures that can be taken to prevent the spread of influenza. These include:

- Washing your hands frequently to avoid the spread of viruses and bacteria;
- Avoiding contact with people who may be sick;
- Cleaning telephones, door knobs, and other environmental surfaces with disinfecting agents to help prevent the spread of viruses and bacteria;
- Covering your mouth and nose when coughing or sneezing;
- Staying home from work and/or school when you are sick and limiting/eliminating contact with those who have compromised immune systems.

In late August 2004, US Department of Health and Human Services (HHS) Secretary Tommy G. Thompson released preliminary plans for a National Pandemic Influenza Preparedness Plan that details a national strategy to prepare for and respond to an influenza pandemic and provides action steps that should be taken at the national, state, and local levels during a pandemic. At press time, the draft plan was located at www.hhs.gov/nvpo/pandemicplan. Pharmacists have become increasingly active in efforts to increase the public access to immunizations; according to National Association of Board's of Pharmacy® (NABP®) 2003-2004 *Survey of Pharmacy Law*, more than half of the states allow pharmacists to administer immunizations.

Because of the influenza vaccine shortage, many have expressed concerns about the possibility of counterfeit influenza vaccines. Pharmacies and health care institutions should only secure product from reputable resources and immediately report any suspect product. Also, many pharmacies have reported that the price of influenza injectable vaccines from some distributors has more than doubled since the shortage. In mid-October 2004, HHS Secretary Thompson urged the state attorneys general to prosecute those who were price gouging the cost of influenza vaccines.

For more information visit these Web sites:

FDA Flu Information – www.fda.gov/oc/opacom/hottopics/flu.html.

CDC Influenza Information (including vaccination information and Antiviral Medication Usage Guidelines) – www.cdc.gov/flu.

FDA Urges Consumer Education About Counterfeit Drugs

In an interim report, FDA's Anti-Counterfeiting Task Force stressed the importance of increasing awareness and education of stakeholders including the public concerning counterfeit drugs. The report called for increasing efforts of FDA and other government agencies to educate consumers and health care professionals on how to reduce the risk of obtaining counterfeit drugs before the event occurs; educating consumers and health care professionals on how to identify counterfeit drugs; and improving and coordinating FDA and industry messages and efforts to address and contain a counterfeit event. At press time, FDA had available on its Web site (www.fda.gov/cder/consumerinfo/counterfeit_all_resources.htm) public service announcements that can be printed for consumers as well as educational articles to inform the public.

One recent high-profile case concerned Viagra® (sildenafil citrate) that was dispensed from two pharmacies located in California. The counterfeit product closely resembled genuine Viagra tablets with respect to size, shape, color, and imprinting; however, the counterfeit drugs had subtle differences in tablet edging, film coating, imprinting font, and packaging. At press time, FDA, along with Pfizer, Inc, the legitimate manufacturer of Viagra, was analyzing the counterfeit product to determine its true composition and whether or not it posed any health risks; fortunately, no injuries had been reported. For comparative photos of the counterfeit drug and genuine Viagra, refer to Pfizer's "Dear Pharmacist" letter posted on the company's Web site at www.pfizer.com as well as FDA's distributed a press release that is now available at www.fda.gov.

Exactly one month after the counterfeit Viagra product was discovered, FDA expressed concern regarding counterfeit versions of the prescription drugs Zocor® (simvastatin) and carisoprodol, which were imported from Mexico by US citizens. Tests of these products revealed that the counterfeit Zocor, reportedly purchased at Mexican border-town pharmacies and sold under the name Zocor 40/mg (lot number K9784, expiration date November 2004, and lot number K9901, expiration date December 2006), did not contain any active ingredient. Likewise, the counterfeit carisoprodol 350/mg (lot number 68348A) test results indicated that the products differed significantly in potency when compared to the authentic product. FDA continues to investigate this matter and is working with Mexican authorities to ensure that further sale and importation of these products are halted. For more information on counterfeit Zocor, visit www.fda.gov/bbs/topics/ANSWERS/2004/ANS01303.html.

Diabetes or Alzheimer's Disease?

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with United States Pharmacopeia (USP) and FDA in analyzing medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, then publishes its recommendations. If you would like to report a problem confidentially to these organizations, go to the ISMP Web site (www.ismp.org) for links with USP, ISMP, and FDA. Or call 1-800/23-ERROR to report directly to the USP-ISMP Medication Errors Reporting Program. ISMP address: 1800 Byberry Rd, Huntingdon Valley, PA 19006. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.

Several reports of mix-ups have been reported in which the antidiabetic agent **AMARYL®** (glimepiride) had been dispensed to geriatric patients instead of the Alzheimer's Disease medication **REMINYL®** (galantamine). Each drug is available in a 4 mg tablet, although other tablet strengths are also available for each.

In one case, a 78-year-old woman with a history of Alzheimer's disease was admitted to the hospital with hypoglycemia (blood glucose on admission 27 mg/dL). A review of the medications she was taking at home revealed that her pharmacist dispensed Amaryl 4 mg, which she took twice daily instead of Reminyl 4 mg BID. In another case, an 89-year-old female received Amaryl instead of Reminyl for three days, eventually requiring hospitalization for treatment of severe hypoglycemia. A third patient received Amaryl instead of Reminyl while in the hospital, leading to severe hypoglycemia. All patients recovered with treatment. These events have been linked to poor prescriber handwriting and sound-alike, look-alike names. It is possible that prescriptions for Amaryl are more commonly encountered than those for Reminyl. Thus, confirmation bias (seeing that which is most familiar, while overlooking any disconfirming evidence) may lead pharmacists or nurses into "automatically" believing a Reminyl prescription is for Amaryl.

Obviously, accidental administration of Amaryl poses great danger to any patient, especially an older patient, who may be more sensitive to its hypoglycemic effects. Practitioners should be alerted to the potential for confusion between Amaryl and Reminyl. Prescribers should be reminded to indicate the medication's purpose on prescriptions. Consider building alerts about potential confusion into computer order entry systems and/or adding reminder labels to pharmacy containers. Patients (or caregivers) should be educated about all of their medications so they are familiar with each product's name, purpose, and expected appearance. Most importantly, at all times pharmacists and nurses should confirm that patients are diabetic before dispensing or administering any antidiabetic medication, including Amaryl. FDA, Aventis (Amaryl), and Janssen Pharmaceutica Products LP (Reminyl) are aware of these reports and will be taking action to help reduce the potential for errors.

Medication Safety Videos Available Free

FDA's Center for Devices and Radiological Health has been producing a monthly series of patient safety videos available via the Internet. ISMP and FDA's Division of Medication Errors and Technical Support, Office of Drug Safety, has been cooperating in this effort. Access www.ismp.org/Pages/FDAVideos.htm for videos related to medication errors. See www.accessdata.fda.gov/scripts/cdrh/cfdocs/psn/viewbroadcasts.cfm for a complete list of all broadcasts.

2005 Survey of Pharmacy Law Now Available

NABP's *2005 Survey of Pharmacy Law* CD-ROM is now available. Eight new questions were added to this year's *Survey;* topics include the formatting requirements of prescription pads, laws/regulations on the disposal of medications, and whether or not pharmacists are allowed to dispense emergency contraception without a prescription.

The *Survey* can be obtained for $20 from NABP by downloading the publication order form from www.nabp.net and mailing in the form and a check or money order to NABP. The CD-ROM is provided free of charge to all final-year pharmacy students through a grant from GlaxoSmithKline. If you do not have Web access or would like more information on the *Survey,* please contact NABP at 847/391-4406 or via e-mail at custserv@nabp.net.

NABP Headquarters Moves to New Location

NABP has moved its Headquarters to 1600 Feehanville Drive, Mount Prospect, IL 60056. The new phone number is 847/391-4406 and the new fax number is 847/391-4502. All printed communications can be sent to the Feehanville Drive address. If you have any questions concerning the Association's new Headquarters, please contact the Customer Service Department at custserv@nabp.net or call 847/391-4406.

Register Now for NABP's 101st Annual Meeting

Register now for NABP's 101st Annual Meeting, May 21-24, 2005, at the Sheraton New Orleans Hotel, New Orleans, LA, so you can take advantage of the chance to earn up to five hours of continuing education (CE).

This year, CE sessions will focus on topics that fall under the Meeting's theme, "A Medley for Patient Safety: Accreditation, Self Assessment, Quality Care." Other events include the Educational Presentation Area and Poster Session, the President's Welcome Reception, NABP's annual business sessions, and the Annual Awards Dinner. In addition, you and your spouse or guest will have the opportunity to participate in a special recreational tour and the annual Fun Run/Walk.

For more information visit NABP's Web site at www.nabp.net, or contact NABP at 847/391-4406 or custserv@nabp.net.

Disciplinary Actions – Board of Pharmacy (actions since July 2004 Newsletter*)*

Notice: *Before making a prescription-dispensing or other decision pursuant to information in this issue, you are encouraged to verify the current condition of a license with the appropriate licensing agency (board).*

Thomas Togno, RPh – Suspension until further notice, substance abuse program participation required: Controlled Substance violations, substance abuse.

Shirley Thompson, RPh – $4,000 Civil Penalty and one-year probation, no preceptor or PIC: during probation: Non-purposeful failure of Controlled Substance accountability.

Kino Community Hospital – $111,802 Civil Penalty and voluntary surrender of pharmacy permit: Failure to account for numerous Controlled Substances as required.

Lisa Hunter, RPh – One-year probation, eight hours of continuing education and $500 civil penalty, no preceptor or PIC during probation: prescription error.

Gregory Mowers, RPh – Six-months to one-year suspension and five-year Pharmacists Assisting Pharmacists of Arizona (PAPA) substance abuse contract: Controlled Substance violations.

Lisa Bueno, RPh – Six-months to one-year suspension and five-year PAPA substance abuse contract: Controlled Substance violations.

Disciplinary Actions – Other Health Care Practitioner Boards

Keven D. Brockbank, MD (#29044) – Summary suspension, effective September 29, 2004.

Mark R. Wade, MD (#23131) – Five-year Probation, effective August 25, 2004.

Walter Jacobs, MD (#3829) – Prescribing Prohibition until further notice, effective September 28, 2004.

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The *Arizona State Board of Pharmacy News* is published by the Arizona State Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, to promote voluntary compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of the Foundation or the Board unless expressly so stated.

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